

THE UNITED STATES PATENT AND TRADEMARK OF

Applicant(s): Yoshinaga

Serial No.:

09/890,729

Group Art Unit No.: Unknown

Filed:

January 27, 2000

Examiner: Unknown

For:

Polypeptides Involved in Immune Response

Docket No.: A-579 B

### INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

As a means of complying with the duty of disclosure, applicant submits a "List of References Cited by Applicant" on a modified PTO-1449 form and provides a copy of each of the listed references for consideration by the Examiner.

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under section 1.114, whichever event occurs last. 37 CFR 1.97(b).

Applicant requests consideration of this information and passage of the application to issue.

The Commissioner is hereby authorized to charge any filing fees which may be required or credit any overpayment to Deposit Account No. 01-0519 in the name of Amgen Inc.

Respectfully submitted.

Robert B. Winter

Attorney/Agent for Applicant(s)

Registration No.: 34, 458 Phone: (805) 447-2425

Date:

Please send all future correspondence to:

US Patent Operations/RBW Dept. 4300, M/S 27-4-A AMGEN INC. One Amgen Center Drive Thousand Oaks, California 91320-1799

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class

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Modified Form PTO-1449

### LIST OF REFERENCES CHEET BY APPLICANT

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| Atty.                 | Serial No.    |
| Docket No. A-579 B    | 09/890,729    |
| Applicant             |               |
| Yoshinaga Yoshinaga   |               |
| Filing                | Group         |
| Date January 27, 2000 | Unknown       |

**U.S. PATENT DOCUMENTS** 

| EXAMINER'S<br>INITIALS |    | DOCUMENT NUMBER | DATE     | NAME             | CLASS | SUB-<br>CLASS | FILING DATE IF<br>APPROPRIATE |
|------------------------|----|-----------------|----------|------------------|-------|---------------|-------------------------------|
|                        | AA | 3,773,919       | 11/20/73 | Boswell et al    |       |               |                               |
|                        | АВ | 4,816,567       | 3/28/89  | Cabilly et al.   |       |               |                               |
|                        | AC | 4,892,538       | 1/9/90   | Aebischer et al. |       | -             |                               |
|                        | AD | 4,970,154       | 11/13/90 | Chang            |       |               |                               |
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|                        | Al | 5,676,954       | 10/14/97 | Brigham          |       |               |                               |

**FOREIGN PATENT DOCUMENTS** 

|            | DOCUMENT NUMBER | DATE     | COUNTRY | CLASS | SUB-  | TRANS | LATION |
|------------|-----------------|----------|---------|-------|-------|-------|--------|
| <br>       |                 |          |         |       | CLASS | YES   | МŌ     |
| ВА         | EP 0 036 676    | 9/19/90  | EPO     |       |       | X     |        |
| B <b>B</b> | EP 0 058,481    | 10/1/86  | EPO     |       |       | х     |        |
| ВС         | EP 0 088 046    | 12/9/87  | EPO     | 1     |       |       | Х      |
| BD         | EP 0 133 988    | 3/13/85  | EPO     |       |       |       | Х      |
| BE         | EP 0 143 949    | 10/12/88 | EPO     |       |       | Х     |        |
| BF         | EP 0 154 316    | 9/13/89  | EPO     |       |       | Х     |        |
| BG         | EP 0 401 384    | 3/13/96  | EPO     |       |       | Х     |        |
| вн         | WO 91/10425     | 7/25/91  | WIPO .  |       |       | Х     |        |
| ВІ         | WO95/11308      | 4/27/95  | WIPO    |       |       | Х     |        |
| BJ         | WO 96/40958     | 12/19/96 | WIPO    |       |       | Х     |        |
| ВК         | WO 98/38216     | 9/03/98  | WIPO    |       |       | X     |        |
| BL         | WO 99/15553     | 4/01/99  | WIPO    |       |       | Х     |        |
| ВМ         | EP 1 125 585    | 8/22/01  | EPO     |       |       | X     |        |

EXAMINER:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Modified Form PTO-1449                  | Atty. Docket No. | Officer 2 of 3 |
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| 111001110011111111111111111111111111111 | Ally. Docker No. | Serial No.     |
|   | A-579 B          | 09/890.729     |
| LIST OF REFERENCES CITED BY APPLICANT   | Applicant        |                |
| '                                       | Yoshinaga        |                |
| (Use several sheets if necessary)       | Filing Date      | Group          |
|   | January 27, 2000 | Unknown        |

EXAMINER'S OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) INITIALS Altschul et al., "Basic Local Alignment Search Tool", J. Mol. Biol. 215, 403-410 (1990) Aruffo and Seed, "Molecular cloning of a CD28 cDNA by a high-efficiency COS cell expression system", Proc. Natl. Acad. Sci. 84, 8573-CB 8577 (1987) Ausubel et al., Current Protocols in Molecular Biology, Green Pub. and Wiley and Sons, NY (1994) TABLE OF CONTENTS CC Brunet et al., "A new member of the immunoglobulin superfamily--CTLA-4", Nature 328, 267-270 (1987) CD Carillo et al., "The Multiple Sequence Alignment Problem in Biology", SIAM J. Applied Math. 48, 1073 (1988) CE Dariavach et al., "Human Ig superfamily CTLA-4 gene: chromosomal localization and identity of protein sequence between murine and CF human CTLA-4 cytoplasmic domains", Eur. Jour. Immun. 18, 1901-1905 (1988) Dayhoff et al., "A Model of Evolutionary Change in Proteins", Atlas of Protein Sequence and Structure, vol. 5, supp. 3 (1978) CG Devereux et al., "A comprehensive set of sequence analysis programs for the VAX", Nucleic Acids Research 12(1), 387 (1984) CH Engels et al., "Gene Synthesis", Angew. Chem. Intl. Ed. 28, 716-734 (1989) CI Eppstein et al., "Biological activity of liposome-encapsulated munne interferon y is mediated by a cell membrane receptor", Proc. Natl. CJ Acad. Sci. USA, 82, 3688-3692 (1985) Francis, "Protein modification and fusion proteins", Focus on Growth Factors 3, 4-10 (1992) CK Freeman et al., "B7, a New Member of the Ig Superfamily with Unique Expression on Activated and Neoplastic B Cells", J. Immunology CL 143, 2714-2722 (1989) Freeman et al., "Structure, Expression, and T Cell Costimulatory Activity of the Murine Homologue of the Human B Lymphocyte Jour. СМ Expt. Med. 174, 625-31 (1991) Freeman et al., "Murine B7-2, an Alternative CTLA4 Counter-receptor that Costimulates T Cell Proliferation and Interleukin 2 Production", Jour. Expt. Med. <u>178,</u> 2185-2192 (1993) Freeman et al., "Cloning of B7-2: A CTLA-4 Counter-Receptor That Costimulates Human T Cell Proliferation", Science 262, 909-911 CO Gennaro, Remington's Pharmaceutical Sciences, 18th Edition, ed., Mack Publishing Company (1990) TABLE OF CONTENTS CP Gribskov et al., Sequence Analysis Primer, eds., M. Stockton Press, New York, 1991 TABLE OF CONTENTS CQ Griffin et al., Computer Analysis of Sequence Data, Part 1, eds., Humana Press, New Jersey, 1994 TABLE OF CONTENTS CR Gross et al., "The Murine Homologue of the T Lymphocyte Antigen CD28", J. Immun. 144, 3201-3210 (1990) CS Henikoff, "Amino acid substitution matrices from protein blocks", PNAS, USA 89, 10915-10919 (1992) CI Hoogenboom et al., "By-passing Immunisation", J. Mol. Biol. 227, 381 (1991) CU Houghten et al., "General method for the rapid solid-phase synthesis of large numbers of peptides: Specificity of antigen-antibody C۷ interaction at the level of individual amino acids", Proc Natl Acad. Sci. USA 82, 5132 (1985) Hutloff et al., "ICOS is an inducible T-cell co-stimulator structurally and functionally related to CD28", Nature 397, 263-266 (1999) Jakobovits et al., "Germ-line transmission and expression of a human-derived yeast artificial chromosome", Nature 362, 255-258 (1993) CX Jakobovits et al., "Analysis of homozygous mutant chimeric mice: Deletion of the immunoglobulin heavy-chain joining region blocks B-cell CY development and antibody production\*, Proc. Natl. Acad. Sci. 90, 2551-2555 (1993) EXAMINER: Date Considered: EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| <br>           | Sheet 3 of 3 |
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| <br>Serial No. |              |
|                | 09/890 729   |
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# LIST OF REFERENCES CITED BY APPLICANT

Modified Form PTO-1449

(Use several sheets if necessary)

| Alty. Docket No. |                  | Serial No. |
|------------------|------------------|------------|
|                  | A-579 B          | 09/890 729 |
| Applicant        |                  |            |
|                  | Yoshinaga        |            |
| Filing Date      |                  | Group      |
|                  | January 27, 2000 | Unknown    |

EXAMINER'S OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) INITIALS Jones et al., "Replacing the complementarity-determining regions in a human antibody with those from a mouse", Nature 321, 522-525 CZ Kitts et al., "A Method for Producing Recombinant Baculovirus Expression Vectors at High Frequency", Biotechniques 14, 810-817 (1993) ĐΑ Langer et al., "Biocompatibility of polymeric delivery systems for macromolecules", J. Biomed. Mater. Res. 15, 167-277 (1981) DВ Langer, "Controlled release of macromolecules", Chem. Tech. 12, 98-105 (1982) DC Lesk, Computational Molecular Biology, ed., Oxnard University Press, New York (1998) TABLE OF CONTENTS חח Lucklow, "Baculovirus systems for the expression of human gene products", Curr. Opin. Biotechnol. 4, 564-572 (1993) DE Lucklow et al., "Efficient Generation of Infectious Recombinant Baculoviruses by Site-Specific Transposon-Mediated Insertion of Foreign DF Genes into a Baculovirus Genome Propagated in Escherichia coli<sup>a</sup>, J. Virol. <u>67</u>, 4566-4579 (1993) Marks et al., "By-passing Immunization Human Antibodies from V-gene Libraries Displayed on Phage", J. Mol. Biol. 222, 581 (1991) DG Marston et al., "Solubilization of Protein Aggregates", Meth. Enz. 182, 264-275 (1990) DH McDonald et al., "Isolation of RNA Using Guanidinium Salts", Meth. Enzymol. 152, 219 (19987) D! Merrifield, "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide", J. Am. Chem. Soc. 85, 2149 (1963) ΟJ Morrison et al., "Chimeric human antibody molecules: Mouse antigen-binding domains with human constant region domains", Proc. Natl. Acad. Sci. 81, 6851-6855 (1985) Neddlemen et al., "A General Method Applicable to the Search for Similanties in the Amino Acid Sequence of Two Proteins", J. Mol. Biol. DL 48, 443-453 (1970) Ogden et al., "Electrophoresis in Agarose and Acrylamide Gels", Meth. Enzymol. 152, 61 (1987) DM Riechmann et al., "Reshaping human antibodies for therapy", Nature 332, 323-327 (1988) DN Sambrook et al., Molecular Cloning: A Laboratory Manual, Cold Springs Harbor Laboratory Press, Cold Springs Harbor, NY (1989) TABLE DO OF CONTENTS Sidman et al, "controlled Release of Macromolecules and Pharmaceuticals from Synthetic Polypeptides Based on Glutamic Acid", Biopolymers 22, 547-556 (1983) Smith, et al., Biocomputing: Informatics and Genome Projects, Academic Press, New York, 1993 TABLE OF CONTENTS DQ Steward and Young, Solid Phase Peptide Synthesis, Pierce Chemical Co., Rockford, IL (1984) TABLE OF CONTENTS DR Verhoeyen et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity", Science 239, 1534-1536 (1988) DS von Heinje, Sequence Analysis in Molecular Biology, Academic Press, (1987) TABLE OF CONTENTS EXAMINER: Date Considered: EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with inext communication to applicant

COPY

PATENT

Customer Number: 22,852

Attorney Docket No. 6843.0050-04000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MAY 1 6 2005

Steven K. YOSHINAGA

Group Art Unit: 1646

Application No.: 09/890,729

Examiner: Not Yet Assigned

Filed: August 3, 2001

For:

POLYPEPTIDES INVOLVED

IN IMMUNE RESPONSE

Assistant Commissioner for Patents Washington, DC 20231

Sir:

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents listed on the attached Form PTO 1449. This Information Disclosure Statement is being filed, to the undersigned's knowledge, before the mailing date of a first Office Action on the merits for the above-referenced application.

Each document listed on the attached Form PTO 1449 was cited in a communication in a counterpart Patent Cooperation Treaty application, and this Information Disclosure Statement is being filed within three months of the mailing date printed on that communication.

Copies of the listed documents are attached.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

FINNEGAN HENDERSON FARABOW GARRETT& DUNNERLLP

1300 I Street, NW Washington, DC 20005 202.408.4000 Fax 202.408.4400 www.finnegan.com This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the claimed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: February 5, 2003

Robert W. Mann

Reg. No. 48,555

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

1300 I Street, NW Washington, DC 20005 202.408.4000 Fax 202.408.4400 www.finnegan.com

### INFORMATION DISCLOSURE CITATION

| Atty. Docket No. | 06843.0050-04000    | Appin. No. | 09/890,729 | 010         |
|------------------|---------------------|------------|------------|-------------|
| Applicant        | Steven K. YOSHINAGA |            |            | MAY 1 6 m S |
| Filing Date      | August 3, 2001      | Group:     | 1646       | 2005        |
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| U.S. PATENT DOCUMENTS |                    |            |      |       |              |                            |
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| Examiner<br>Initial*  | Document<br>Number | Issue Date | Name | Class | Sub<br>Class | Filing Date If Appropriate |
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| · | Document<br>Number | Publication<br>Date | Country      | Class | Sub<br>Class | Translation<br>Yes or No |
|   | WO 00/46240        | 08/10/2000          | PCT          |       |              | <u>.</u>                 |
|   |                    |                     |              |       |              | · ·                      |

| <br>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)   |
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| <br>Ling et al., "Cutting Edge: Identification of GL50, a Novel B7-Line Protein That Functionally Binds to ICOS Receptor," <i>Journal of Immunology</i> , 164(4):1653-1657 (2000). |
| <br>Tafuri et al., "ICOS is Essential for Effective T-Helper-cell responses," Nature, 409:105-109 (2001)   |
| Wang et al., "Costimulation of T cells by B7-H2, a B7-like Molecule that Binds ICOS," Blood, 96(8):2808-2813 (2000).   |
| Yoshinaga et al., "T-cell Co-stimulation Through B7RP-1 and ICOS," Nature, 402:827-832 (1999).   |
| International Search Report for PCT Application No. PCT/US01/44859, mailed December 3, 2002.   |
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